

REMARKS

Claims 45-65 are pending in the subject application. By this Amendment, Claim 45 has been amended. Applicants maintain that the amendments do not raise an issue of new matter. Support for amendments to Claim 45 can be found in the application at least on page 43, line 7 through page 44, line 19, and in Fig. 3 (b) and (c). Accordingly, entry of the amendments is respectfully requested.

Obviousness-type Double Patenting Rejections based on U.S. Patent 6,875,327

Claims 45 and 47 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 10 of U.S. Patent No. 6,875,327.

Claim 46 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 11 of U.S. Patent No. 6,875,327.

Claim 49 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 3 and 10 of U.S. Patent No. 6,875,327.

Claim 50 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 4 and 10 of U.S. Patent No. 6,875,327.

Claim 51 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 5 and 10 of U.S. Patent No. 6,875,327.

Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 6 and 10 of U.S. Patent No. 6,875,327.

Claim 53 is rejected on the ground of nonstatutory obviousness-type double

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patenting as allegedly being unpatentable over Claims 7 and 10 of U.S. Patent No. 6,875,327.

Claim 54 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 8 and 10 of U.S. Patent No. 6,875,327.

Claim 55 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 9 and 10 of U.S. Patent No. 6,875,327.

Claim 56 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 12 of U.S. Patent No. 6,875,327.

Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 13 of U.S. Patent No. 6,875,327.

Claims 58 and 59 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 14 of U.S. Patent No. 6,875,327.

Claim 60 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10, 14 and 15 of U.S. Patent No. 6,875,327.

Claim 61 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10, 14 and 16 of U.S. Patent No. 6,875,327.

Claim 62 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 18 of U.S. Patent No. 6,875,327.

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Claims 63 and 64 are rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 19 of U.S. Patent No. 6,875,327.

Claim 65 is rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 10 and 20 of U.S. Patent No. 6,875,327.

Applicants attach hereto a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) in order to remove the double patenting rejections over U.S. Patent No. 6,875,327. The fee for submitting a Terminal Disclaimer is \$140.00, and a check including this amount is enclosed. In view of the Terminal Disclaimer attached hereto, applicants respectfully request withdrawal of these double patenting rejections.

Obviousness-type Double Patenting Rejections based on co-pending U.S. Patent Application No. 10/809,240

Claims 45, 46, 56 and 58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 47 of co-pending U.S. Patent Application No. 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 47 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 49 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 48 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 50 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 49 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 51 of co-pending U.S. Patent

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Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 50 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 52 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 51 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 53 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 52 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 54 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 53 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 55 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 54 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 56 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 55 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 57 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 57 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claim 48 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 59 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 58 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 60 is provisionally rejected on the ground of nonstatutory obviousness-type

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double patenting as allegedly being unpatentable over Claims 47 and 60 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 61 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 61 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 62 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 62 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 63 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 63 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 64 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 64 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Claim 65 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over Claims 47 and 65 of co-pending U.S. Patent Application 10/809,240 in view of Winarta et al., U.S. Patent No. 6,287,451.

Applicants attach hereto a Terminal Disclaimer in compliance with 37 C.F.R. §1.321(c) in order to remove the double patenting rejections over co-pending U.S. Patent Application 10/809,240. The fee for submitting a Terminal Disclaimer is \$140.00, and a check including this amount is enclosed. In view of the Terminal Disclaimer attached hereto, applicants respectfully request withdrawal of these double patenting rejections.

Rejections under 35 U.S.C. §102(e)

Claims 45, 53-55 and 62-65 are rejected as being anticipated by Winarta et al. (US Patent No. 6,287,451) ("Winarta").

The invention according to amended claim 45 comprises a first insulating support and a second insulating support, and electrode part providing at least a working electrode and a counter electrode, a specimen supply path for introducing the sample liquid to the electrode part, and a reagent layer employed for quantifying the substrate included in the sample liquid, and is characterized in that the electrode part is dividedly formed by providing a first type of slits, the reagent layer (14, Fig. 3) is formed by dripping a reagent and positioned on the electrode part, and a second type of slits is provided around a position where the reagent is dripped so as to partly surround the dripped position (24a and 24b, Fig. 3).

According to the invention of amended claim 45, it is possible to make an adjustment, by the second type of slits, such that the amount of the reagent formed on the electrode becomes uniform and thereby prevents the measurement accuracy from varying among different biosensors produced.

This feature addresses an important problem. When biosensors are mass-produced, it is difficult to control the amount of liquid reagent dripped from a dispenser with high precision, and variations in the amount of the dripped reagent can occur in many cases. If the amount of the dripped sample varies, the amount of reagent formed on the electrode part would vary, thereby measurement result would vary for every biosensor. When the amount of the dripped sample is large, the measurement result becomes large.

However, according to the invention of amended claim 45, since the second type of slits partly surround the position where the reagent is dripped, even when the amount of the dripped reagent becomes excessive, the excessive reagent adequately flows from the

part where the second type of slit is not formed, and it is possible to make an adjustment so that the amount of reagent for measurement is uniform. Thus, it is possible to produce high-accuracy biosensors.

In contrast, Winarta discloses a biosensor comprising a base layer 20, a first middle layer 30, a second middle layer 40, and a top layer 50. Winarta discloses that the first middle layer 30 provides a first electrode cutout 32, a second electrode cutout 34, and a third electrode cutout 36. Winarta also discloses that three cutouts 32, 34 and 36 respectively define the electrode area W1, R and W2, and hold chemical reagent which forms two working electrodes and one reference electrode. Further, Winarta discloses that an additional scoring line 28 may be provided along the outer edge of base layer 20 in order to avoid static electricity problems that could generate noise signals.

The Examiner indicates that the scoring line 28 of Winarta corresponds to the second type of slits of the present invention. However, the scoring line 28 of Winarta is completely different from the second type of slits of the present invention according to amended claim 45.

The second type of slits of the invention according to amended claim 45 is provided around a position where the reagent is dripped so as to partly surround the dripped position, as shown in Fig. 3 (b) and (c) of the present application.

In contrast, as shown in Fig. 2 of Winarta, the scoring line 28 of Winarta is provided along the outer edge of base layer 20, and the scoring line 28 is not one which partly surrounds a position where the reagent is dripped on the electrode. As described above, in Winarta, the reagent is held by three cutouts 32, 34 and 36, and the scoring line 28 is not one which partly surrounds a position where the reagent is dripped.

Further, as described above, the second type of slits of the invention according to amended claim 45 can make the amount of the reagent for measurement uniform by partly surrounding a position where the reagent is dripped. In contrast, since the scoring

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line 28 of Winarta is provided along the whole of outer edge of the base layer 20, Winarta cannot obtain the effect of the invention according to amended claim 45.

As described above, the scoring line 28 of Winarta is completely different from the second type of slits of the present invention.

Applicants maintain that the invention according to amended claim 45 is not anticipated by Winarta. Similarly, claims 46-65, which depend from amended claim 45, are not anticipated by Winarta.

Reconsideration and withdrawal of these rejections are respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 46, 47, 49, and 51 are rejected as being unpatentable over Winarta in view of Ikeda et al. (U.S. Patent No. 5,582,697).

Claim 50 is rejected as being unpatentable over Winarta in view of Kawaguri et al. (U.S. Patent No. 5,171,689).

Claims 56-60 are rejected as being unpatentable over Winarta in view of Kawanaka (U.S. Patent No. 6,599,406).

Claim 61 is rejected as being unpatentable over Winarta in view of Kawanaka and further in view of Fujiwara et al. (U.S. Patent No. 6,004,441).

Applicants maintain that none of the cited references disclose or suggest the second type of slits of the invention according to amended claim 45, as discussed above. Similarly, claims 46-65, which depend from amended claim 45, are not obvious over the cited references.

Reconsideration and withdrawal of these rejections are respectfully requested.



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Supplemental Information Disclosure Statement

This Information Disclosure Statement is being filed to supplement the Information Disclosure Statements filed on March 25, 2004, April 16, 2007, August 15, 2008 and October 14, 2008 in connection with the above-identified application.

In accordance with the duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the references that are listed on the attached form PTO/SB/08A.

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### CONCLUSIONS

In view of the amendments and remarks made hereinabove, reconsideration and withdrawal of the rejections in the October 17, 2008 Office Action and passage of the pending claims to allowance are respectfully requested. If there is any minor matter preventing the allowance of the subject application, the Examiner is requested to telephone the undersigned attorney.

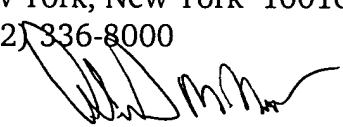
A check for \$590.00 is enclosed for the \$130.00 fee for a one month extension of time, the \$180.00 fee for submitting an Information Disclosure Statement, and the \$280.00 fee for submitting two Terminal Disclaimers (\$140.00 each). No other fee is deemed necessary in connection with the submission of this reply. However, if an additional fee is required in connection with this submission or to maintain the pendency of the subject application, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 01-1785. Overpayments may be credited to Deposit Account No. 01-1785.

Respectfully submitted,

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By

  
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